

**REMARKS****Claim Amendments**

Claims 1, 2 and 19-23 have been amended. Following this Amendment, claims 1-17 and 18-26 will be pending. Of these, claims 5-17 have been withdrawn from consideration.

Claims 1 and 2 have been amended to add the steps of determining whether an agent inhibits or attenuates hedgehog/patched signal transduction thereby inhibiting or reducing cell proliferation or growth as compared to a control and determining whether an agent promotes hedgehog/patched signal transduction thereby inducing the formation of, or the maintenance or functional performance of normal lung tissue, as compared to a control, respectively. In addition, the preambles of claims 1 and 2 have been amended to recite that the claims are directed to methods for screening for an agent having the previously-recited activities. Support for the amendment can be found, for example, at page 48, line 3 through page 49, line 18 of the specification.

Claims 1, 2 and 19-22 have been amended to recite *ptc* therapeutic instead of *ptc* therapeutic. Support for the amendment can be found, for example, at page 12, lines 17-22 of the specification.

Claim 23 has been amended to delete the recitations of 8-bromo-cAMP and butyryl-cAMP.

No new matter has been added.

**Amendment Mailed May 17, 2006**

The Examiner states that no claim amendments were made on May 19, 2006. Applicants wish to correct the record, in that the dependency of claim 21 was amended in the Amendment received on that date. The present claim listing incorporates that amendment.

**Election/Restriction**

The Examiner's comments are acknowledged. Because claims 1 and 2 serve as linking claims for the claims currently withdrawn from consideration based upon an election of species

and Applicants believe the linking claims to be allowable, Applicants have not canceled the withdrawn claims.

### Withdrawn Objections and Rejections

Applicants acknowledge with appreciation the withdrawal of the objections to and/or rejections of pages 3 and 4 of the specification and claims 1-4, 18 and 19-21.

### Objection to Claims 1, 2 and 19-22

Claims 1, 2 and 19-22 are objected to for reciting the term "ptc therapeutic." Claims 1, 2 and 19-22 have been amended to recite "*ptc* therapeutic," which is defined at page 12, lines 17-22 of the specification, as suggested by the Examiner. This amendment is not believed to change the intended scope of the claims. Withdrawal of the objection is respectfully requested.

### Rejection of Claims 1-4 and 19-26 Under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 1-4 and 19-26 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicants respectfully traverse the rejection, to the extent that it applies to the claims as amended.

The Examiner states that the specification and prior art do not identify any small organic molecules that can inhibit lung cancer cell growth or proliferation. The Examiner also states that even if a particular compound is identified as a hedgehog/patched pathway inhibitor, it is not predictable whether or not it will inhibit lung cancer cell growth or induce the formation of functional lung tissue without further screening to test such inhibition. Claims 1 and 2, the only independent claims pending, have been amended to be directed to methods for screening for agents. Claim 1, as amended, is directed to a method for screening for an agent for inhibiting or reducing the proliferation or growth of lung cancer cells, which includes the steps of contacting the cells with an amount of the agent, where the agent is a *ptc* therapeutic and where the agent is a small organic molecule, and determining whether the agent inhibits or attenuates hedgehog/patched signal transduction thereby inhibiting or reducing cell proliferation or growth, as compared to a control. Claim 2, as amended, is directed to a method for screening for an agent for inducing the formation of, or the maintenance or functional performance of normal

lung tissue, comprising contacting the lung tissue with an amount of an agent, wherein the agent is a *ptc* therapeutic, and determining whether the agent promotes hedgehog/patched signal transduction thereby inducing the formation of, or the maintenance or functional performance of normal lung tissue, as compared to a control. Accordingly, the bases for the rejection are not applicable to the claims as amended, because a skilled artisan need not identify small organic molecules having the recited activity prior to performing the claimed method. Moreover, the specification adequately enables a skilled artisan to perform the recited methods for screening for molecules (including small organic molecules) having the recited activities. See, for example, page 48, line 3 through page 49, line 18.

With respect to claim 23, the recitation of "8-bromo-cAMP" and "dibutyryl-cAMP" have been deleted in order to expedite prosecution.

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1-4 and 19-26 Under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 1-4 and 19-26 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully traverse the rejection, to the extent that it applies to the claims as amended.

The Examiner states that the specification does not describe examples of compounds that work in the claimed methods. As discussed above, the independent claims have been amended to be directed to methods for screening for agents. For this reason, the bases for the rejection are no longer applicable to the claims as amended. Moreover, the specification adequately discloses methods for screening for molecules (including small organic molecules) having the recited activities. Reconsideration and withdrawal of the rejection are requested.

Rejection of Claim 23 Under 35 U.S.C. § 112, Second Paragraph

Claims 23 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that claim 23 is indefinite because the list of protein kinase A inhibitors includes 8-bromo-cAMP and dibutyryl-cAMP. In order to expedite prosecution, claim

23 has been amended to delete the recitation of 8-bromo-cAMP and dibutyryl-cAMP.


Withdrawal of the rejection is respectfully requested.

**CONCLUSION**

If any clarification of the above response would facilitate prosecution of this application, Applicants respectfully request that the Examiner contact the undersigned at 617-951-7000. Any fee required for timely consideration of this submission may be charged to **Deposit Account No. 18-1945, under Order No. HUIP-P02-032.**

Respectfully Submitted,

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